

Food and Drug Administration
Dockets Management Branch (HFA-305)
Room 1061
5630 Fishers Lane
Rockville, MD 20852

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Docket No. 94P-0036, CFSAN 9727. Food Labeling: Trans Fatty
Acids in Nutrition Labeling,
Nutrient Content Claims, and Health Claims. [PRE-PUB]

Dear Commissioner:

I am writing specifically in response to the FDA's request
for comments on proposed implementation of trans-unsaturated
fatty acid labeling policy, in particular on the issues
discussed on pages 30-34 of the above-referenced document.

I support the breakout of trans-fatty acids in the labeling
of foods, however, object to their de facto characterization
as a form of saturated fat.

It is noted with appreciation that the FDA is wary (p 31) of
petitioner's approach of modifying the regulatory definition
of saturated fat to include trans-unsaturated fatty acids.
The FDA correctly observes that this would be scientifically
inaccurate. Nevertheless, the compromise proposal does not
overcome this criticism. The sample label of Fig. 1, for
example, indicates three types of fat: saturated,
polyunsaturated, and monounsaturated, but uses an asterisk
to indicate that the "saturated fat" quantity "includes . . .
trans fat".

This consumer appreciates the reasoning that the FDA has set
forth supporting this proposal, but is concerned that the
effort to minimize consumer confusion will merely help
perpetuate the same. Would consumers truly be less confused
about trans-unsaturated fats if a government agency deems
them to be a form of saturated fat? Consider that
petitioner is in effect using membership in the saturated
fat category as indicative of unhealthful properties, and by

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extension implying that unsaturated fats do not have unhealthful properties. Would consumers be less confused if a federal agency implicitly took the position that a fat is innocuous merely by virtue of being unsaturated? Since trans-fatty acids are inherently unsaturated, and they are deemed to be not innocuous by the FDA, to do so would be sending a message other than what the agency intends.

The FDA cites a 1995 survey (p 31) indicating that "almost 90% of consumers' . . . do not understand that trans fatty acids raise serum cholesterol levels". In view of the proliferation of articles in the popular press, and the recent appearance of such things as "trans-fat-free" products on grocery store shelves, extrapolation of the results of a 1995 survey to 2000 and beyond is tenuous at best. More to the point, even if that were representative of current consumer misunderstanding, the question remains of how to best address it. Petitioner seems to invoke the implicit assumption that a labeling device along the lines of what petitioner proposes is the only available means. But if the problem were indeed a lack of consumer awareness on the cholesterolemic properties of trans fatty acids, the solution would be to improve that lack of public awareness. Petitioner instead advocates capitalizing on, and in the process reinforcing, its presumed public ignorance.

To accept petitioner's approach, one first has to give up on the idea that consumer knowledge of nutrition is an evolving, ever more sophisticated body of understanding. Petitioner itself is actively engaged in public education as to the role of trans-fat in CHD, yet seems to presuppose its own failure by asking the FDA to simply equate it with saturated fat. In actuality, through its petition petitioner seems to be seeking to assume the role of an "enabler" of consumer confusion, i.e. a facilitator of ignorance via the means of oversimplification. Suppose for a moment that when it was first established that saturated fats had a role in CHD development, rather than enlighten the consumer, it had been decided to give up in advance and just include two sections on the label, "good stuff" and "bad stuff". If this sounds ludicrous, consider that this is effectively what petitioner seeks to do, merely using the term "saturated fat" as a surrogate for "bad stuff".

To put this in perspective, it is also important to appreciate that the history of scientific knowledge on the role of diet and heart disease has itself been an evolving one. Early on, cholesterol was singled out as the principal CHD culprit. Later, it was recognized that serum cholesterol was heavily influenced by dietary saturated fat. Still later, it became appreciated that monounsaturated and polyunsaturated fatty acids were worthy of distinct classification with regard to health effects, and unsaturated fats were accordingly distinguished. The maligned serum cholesterol itself eventually had to be divided into subcategories (according to carrier lipoproteins), in the face of incontrovertible evidence that not only was serum cholesterol not all uniformly malevolent, but that some may be actually beneficial.

We now know that even these more refined classifications of dietary lipids are at best, useful broad-brush approximations, but too often, misleading broad-brush approximations. Among saturated fatty acids, for example, stearic acid is known to be remarkably non-atherogenic, while others are highly atherogenic. Among polyunsaturated fatty acids, the subcategory of omega-3 fatty acids has been identified as playing a unique role in health, while unsaturated fatty acids of the trans variety are found to be atherogenic. The difficulty with making easy "good-guy" and "bad-guy" simplifications becomes yet more clear when one's perspective broadens beyond CHD; for example, some research has implicated high intakes of polyunsaturated fatty acids as risk factors in cancer, even as some are recognized as essential to human nutrition. In addition, the variation of response among individuals to these dietary components belies a one-size-fits-all approach; it is also well known that many individuals, for example, maintain very low levels of serum cholesterol despite relatively high intakes of saturated fats, while conversely, others are unable to maintain recommended levels even with strict adherence to dietary guidelines.

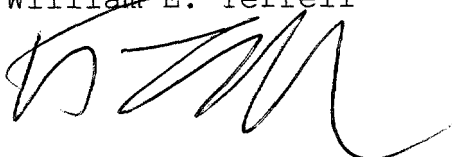
Given the complexity and evolving nature of our understanding of dietary fats, it would be the height of arrogance to assume that here, in 1999, we finally know everything we need to know to write into federal regulation implied value judgments on the scores of fatty acids found

in human nutrition based on their division into three simple categories. This consumer strongly advocates a "Nutrition Facts" label that does exactly what it purports to do, give the facts, no more, no less. It is an entirely separate undertaking to educate the public on the interpretation of those facts, and one appropriately undertaken by the health science professions and the media. It would be a breach of faith with consumers for the agency to lend its regulatory power to a special interest group for the purpose of codifying the latter's judgement as fact. Even assuming arguendo ample scientific reason to support that trans fatty acids are nutritionally similar to saturated fats (and even then with regard to one specific disease process), that is distinctly different from being the same. Given petitioner's approach to fatty acids, it is sobering to consider what tack it might take if tomorrow it were scientifically demonstrated that the amino acid asparagine had similar hypertensive effects as sodium in a large population of individuals.

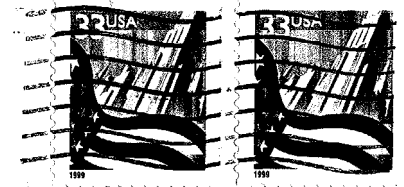
Concerns about distracting consumers from years of consumer education messages focussing on saturated fat should be readily discounted. It is submitted that less emphasis should be placed on salvaging the credibility of past education efforts and more on making those going forward the best they can be. If past understanding turns out to be imprecise or incomplete with the discovery of new scientific evidence, progress demands a willingness to change the message in light of that that new knowledge, not merely try to shoehorn it into an aging and flawed paradigm.

But in the final analysis, it should be enough that trans fats are unsaturated fats, and that to represent them instead as saturated on a label entitled "Nutrition Facts" would undermine the credibility of that very label. Whatever is done with "Nutrition Facts", please preserve it as a sanctuary of facts and resist efforts to infuse it with the agenda of special interests. It should be enough that to portray trans-unsaturated fatty acids as saturated would be simply wrong.

Sincerely,
William E. Terrell

A handwritten signature in black ink, appearing to be 'W. E. Terrell', written in a cursive style.

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